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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

EVANISKO, GEORGE ROBERT

ART UNIT	PAPER NUMBER
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3762

MAIL DATE	DELIVERY MODE
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11/26/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/073,968

Applicant(s)

SCHWEICH ET AL.

Examiner

George R. Evanisko

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 September 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 15-36, 38-45, 47-55, 57-60 and 63-79 is/are pending in the application.
- 4a) Of the above claim(s) 15-33, 50, 51 and 63-79 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 34-36, 38-45, 47-49, 52-55 and 57-60 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 9/14/07.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application
- ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Claims 15-33, 50, 51, and 63-79 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 12/18/06.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 34-36, 38-45, 47-49, 52-55, and 57-60 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claimed invention is claiming a connection to the body since they state that the members are “positioned on an epicardial surface of the heart” and have “an elongate member that extends across the at least one chamber”. Apparatus claims can not claim connection to the body and are therefore directed to non-statutory subject matter.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 34-36, 38-45, 47-49, 52-55, and 57-60 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claims 34, 40, 41, and 42 are vague since they sound as if they are claiming a connection to the body or sound like a method step since they state that the members are “positioned on an epicardial surface of the heart” and have “an elongate member that extends across the at least one chamber”. Apparatus claims can not claim connection to the body and it is suggested to use something similar to “for positioning...”, “configured to be positioned” or “adapted to be positioned”.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 34-36, 38-45, 47-49, 52-54, and 57-60 are rejected under 35 U.S.C. 102(b) as being anticipated by O'Connor (5450860).

O'Connor discloses a ligament, 12, (the claimed connector) that is approximately 10-20 cm, elongated, is capable of extending across at least one chamber due to its size, and can be cut to the proper size of the application (e.g. col. 5, lines 54-65), the use of sutures/pledgets (e.g. 40, 42, 48) at both ends (the claimed members) and other places along the ligament (e.g. col. 10, lines 48-55) and shows that the ligament can have an elongated or circular pledget/member having holes in figures 16, 17, 6, etc. For claims 36-39 and 60, the second connector is considered to be one of the pledgets since it joins the members through the ligament, is encased in heart

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tissue and is straight. Finally, O'Connor is capable of meeting the functional use recitations presented in the claim, such as having at least two portions of the outer wall displaced inwardly from the unrestricted portion, reconfigure the chamber, being located at the anterolateral surface, etc., since O'Connors ligament and sutures are used on heart valves, can be used for other applications (e.g. col. 7, line 20, col. 10), and is capable of being placed through the heart chamber and sutured to the epicardial surface using the sutures and/or pledgets to obtain the claimed intended use recitations. It is noted that the size of the heart the claimed device is meant for, the size of the device, and/or whether it is a animal or human heart has not been set forth in the claims and therefore the size of the device used in O'Connor is not particularly relevant as long as it can meet the structural elements and is capable of meeting the functional use recitations presented in the claims.

Claims 34-36, 38-45, 47-49 and 58-60 are rejected under 35 U.S.C. 102(e) as being anticipated by Fleischman et al (6132438).

Fleischman discloses a suture, 126, (the claimed connector) that is tied to each member, (and therefore each is considered a separate first or second connector) and goes through the heart wall (figure 32 b) and shows the convex shaped members, 120, and how they can be substituted for the members, 116, in figures 31a and 31b. Also for claims 36-39 and 60, the second connector is consider to be the combination of an anchor and suture since it joins the members through the suture, is encased in heart tissue and is straight.

In addition, another interpretation of Fleischman is that Fleischman discloses in figures 31a, b, and c the plurality of members (far left and right anchors, 116) and connectors (suture 126, each connected to separate anchors, in combination with top and bottom anchors 116).

It is noted that the claim does not state that the second connector directly joins the members. Finally, Fleischman is capable of meeting the functional use recitations presented in the claim, such as having at least two portions of the outer wall displaced inwardly from the unrestricted portion, reconfigure the chamber, being located at the anterolateral surface, etc., since Fleischman's suture and anchors are used on the heart and the suture and anchors are capable of being placed through the heart chamber with the anchors being used on the epicardial surface and the suture tightened to obtain the claimed intended use recitations. It is also noted that the size of the heart the claimed device is meant for, the size of the device, and/or whether it is a animal or human heart has not been set forth in the claims and therefore the size of the device used in Fleischman is not particularly relevant as long as it can meet the structural elements and is capable of meeting the functional use recitations presented in the claims.

Claims 34-36, 38-45, 47-49, 52-55, 57, 59, and 60 are rejected under 35 U.S.C. 102(e) as being anticipated by Melvin (5957977).

Melvin discloses cords and elements, e.g. 86, 53, 58, 54, that function as elongated connectors between each member (e.g. 70 A and 70B, figures 2 and 6) with the members being circular, convex, and/or pad like (e.g. figure 5A, 6). As seen in figure 6, Melvin's elongated connector, such as the combination of elements 86, 52, and cord attached to bottom pad 80, extends across at least one chamber.

Melvin is capable of meeting the functional use recitations presented in the claim, such as having at least two portions of the outer wall displaced inwardly from the unrestricted portion, reconfigure the chamber, being located at the anterolateral surface, etc., since Melvin device is used on the heart, is capable of being inflated and maintained at the pressure, applying uniform pressure or applying an indentation against one point (e.g. col. 3, lines 45-52). In addition, it is noted that the use of "static" occurs in the preamble.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 55 is rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over O'Connor (or claim 57 of Fleishman). O'Connors sutures and pledgets are meant for the heart and to be implantable and therefore are biocompatible. In

addition, O'Connor uses an example of CV-2 Goretex suture which is biocompatible. (Fleishman is also meant to be implanted and therefore the connector would be biocompatible)

In the alternative, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the implantable device of O'Connor (or Fleishman) with biocompatible materials since it was known in the art that implantable devices use biocompatible materials to provide the predictable results of not having the body reject the device and so that an infection does not occur.

Response to Arguments

Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection. It is noted that the claims contain numerous functional use recitations. In other words, the claimed invention is just two implantable pads/members and a line connecting them, which is met by the art cited above and numerous other references. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In addition, the size of the heart the claimed device is meant for, the size of the device, and/or whether it is a animal or human heart has not been set forth in the claims and therefore the size of the devices used in the prior art is not particularly relevant as long as the devices can meet the claimed structural elements and are capable of meeting the functional use recitations presented in the claims.

The recitation of "static" has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it

merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

The argument that O'Connor does not meet the claimed limitations of being "positioned on an epicardial surface of the heart" is not persuasive since this is a functional use recitation which is met by O'Connor as discussed above. The argument that Fleischman does not disclose sutures that extend across a heart chamber is not persuasive since the size of the heart chamber or size of the device has not been claimed and is a relative size which is met by the device of Fleischman since his device could be used on a rats, rabbits, pigs, etc heart chamber to extend across the chamber. The argument that Melvin's device does not contain an elongate member to extend across a heart chamber is not persuasive since Melvin's device does extend across a heart chamber as described above in the prior art rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

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CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to George R. Evanisko whose telephone number is 571 272 4945.

The examiner can normally be reached on M-F 6:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571 272 4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

George R Evanisko
Primary Examiner
Art Unit 3762

11/16/07

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